



MassBiologics

Medicine for Better Lives



October 1, 2015

Honorable Steven T. James
Clerk of the House of Representatives
Room 145
State House
Boston, MA 02133

Honorable William F. Welch
Clerk of the Senate
Room 335
State House
Boston, MA 02133

Dear Mr. James and Mr. Welch:

As required by Chapter 75, Section 43(f), we are pleased to "submit to the Clerks of the Senate and the House of Representatives, a report of the activities of Mass Biologics within ninety days after the end of the fiscal year." This is the nineteenth year of such annual reports required by the legislation, which transferred MassBiologics from the Department of Public Health to the University of Massachusetts.

If you have any questions, please contact John Finch, MassBiologics, 460 Walk Hill St., Boston, MA 02126, (617) 474-3251.

Sincerely,

A handwritten signature in blue ink, reading 'Michael F. Collins'.

Michael F. Collins, M.D.
Chancellor
University of Massachusetts Medical School

A handwritten signature in blue ink, reading 'Mark S. Klempner M.D.'.

Mark S. Klempner, M.D.
Executive Vice Chancellor, MassBiologics
University of Massachusetts Medical School

**A REPORT OF THE ACTIVITIES OF MASSBIOLOGICS
FISCAL YEAR 2015**

AS REQUIRED BY CHAPTER 75, SECTION 43(F)

**SUBMITTED TO
CLERK OF THE HOUSE OF REPRESENTATIVES**

&

CLERK OF THE SENATE

October 1, 2015

BY

**MASSBIOLOGICS of the
UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL**

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1. INTRODUCTION

This report is submitted, as required by Chapter 75, Section 43(f), on the activities of the MassBiologics of the University of Massachusetts Medical School. This is the nineteenth year of such annual report.

The following sections provide the required information as follows:

Part 2, Prior Fiscal Year (FY15) Information, as indicated by legislation, describes the patents and licenses, agreements entered into, status of existing agreements, royalties and other benefits, and expenditures, current assets and liabilities. This section includes two schedules: (1) FY15 Balance Sheet and (2) FY15 Statement of Revenues and Expenditures and Other Charges. Included here is information related to appropriated funds for the prior fiscal year, as required by the legislation.

Part 3, Financial Plans, presents projected revenues and expenses. A three-year projection is included.

2 PRIOR FISCAL YEAR (FY15) INFORMATION

This section of the report presents the specific information indicated in the legislation related to the prior fiscal year (FY15: July 1, 2014 - June 30, 2015). This is the nineteenth full year in which MassBiologics has operated within the University of Massachusetts. The effective date of the transfer to the University of Massachusetts was January 1, 1997.

a. Patents and Licensing

MassBiologics has had eight patents with claims allowed in FY15:

Antibodies Against Clostridium Difficile Toxins and Uses Thereof

- 1) 2/31/2014 European Patent No. 2270045
- 2) 3/27/2015 Japanese Patent No. 5717300

Human Antibodies Against Rabies and Uses Thereof

- 1) 4/30/2014 South African Patent No. 2007/07339(notified March 13, 2015)
- 2) 7/25/2014 Hong Kong Patent No. HK1104060

Human Antibodies Against Hepatitis C Virus (HCV) and Uses Thereof

- 1) 7/25/2014 Hong Kong Patent No. HK1138297
- 2) 11/7/2014 Japanese Patent No. 5642972
- 3) 4/14/2015 Canadian Patent No. 2,768,888
- 4) 4/29/2015 Korean Patent No. 1518081

b. Agreements entered into

MassBiologics entered into a new exclusive distribution agreement with Grifols Worldwide Operations Ltd. for the distribution of Tetanus and Diphtheria vaccine for a one year term ending June 30, 2016.

MassBiologics entered into a series of research and collaboration agreements as follows:

- 1) Voyager Therapeutics Inc. – Strategic Collaboration Agreement for adeno associated virus (AAV) products, effective 10/20/2014
- 2) Life Technologies Corporation – Cell Line Services License agreement effective 12/19/2014
- 3) Life Technologies Corporation – Commercial Production License effective 5/1/2015
- 4) AbCellera Biologics Inc. – materials transfer and collaborative research (ETEC) effective 10/6/2014
- 5) Adimab, LLC – materials transfer and collaborative research (Ebola) effective 2/9/2015
- 6) Scripps Research Institute – materials transfer and collaborative research (Ebola) effective 2/13/2015
- 7) Tufts University – research collaboration (Lyme) effective 5/1/2015

MassBiologics signed Master Service Agreements with 2 new biopharmaceutical companies (client names withheld per non-disclosure agreements), executed 41 work order agreements that will generate \$10,342,106 in new revenue, while continuing to build a pipeline of new potential customers for its contract manufacturing services. MassBiologics opened its new South Coast Vector Manufacturing Center and signed a long term development contract for the production of cutting edge gene therapy products with its first client.

c. Grants and Contracts Awarded

DARPA – Award of \$4,379,245 was received from Defense ADV Research Projects Agency effective July 1, 2013 through May 30, 2017. \$2,210,905 of funding was received in FY15.

R24 Grant - Award of \$1,332,331 was received from National Institutes of Health effective May 29, 2013 through April 30, 2015 and this grant received a no cost extension through January 31, 2016. \$618,149 of funding was received in FY15.

NIH Contract - Award of \$3,568,089 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective September 29, 2013 through September 28, 2015. \$1,679,523 of funding was received in FY15.

NIH Grant – Award of \$762,436 was received from NIH-Nat'l Inst. of Allergy & Infectious Disease effective May 1, 2014 through April 30, 2017. \$443,072 of funding was received in FY15.

MLSC Grant – Award of \$5,000,000 was received from Massachusetts Life Sciences Center effective July 1, 2014 through June 30, 2016. \$3,189,961 of funding was received in FY15.

EOHED Grant – Award of \$5,000,000 was received from MassWorks Infrastructure Program effective December 10, 2014 through June 30, 2016. \$954,742 of funding was received in FY15.

d. Status of existing agreements, royalties and other benefits

MassBiologics had the following major existing agreements in FY15.

Bristol-Meyers Squibb, formerly Medarex - a collaborative development agreement had previously been signed April 17, 2002 with a public company (Medarex). This agreement remains in place in support of MassBiologics' continued research.

The Materials Cooperative Research and Development Agreement (M-CRADA) that was entered into January 30, 2004 with the CDC for Rabies was extended until January 30,

2006. Subsequently, that agreement evolved into an Inter-institutional Agreement that was executed in August, 2005.

Merck Exclusive License Agreement April 20, 2009 for antibodies against *C. Difficile*. This agreement remains in place in support of continued clinical development of MassBiologics' proprietary CDiff antibodies.

Serum Institute of India License and Collaboration Agreement effective September 27, 2006. This agreement remains in effect for the development and commercialization of a rabies monoclonal antibody for the treatment of rabies.

Grifols Inc. – Research Collaboration and License effective 5/17/2014 for the development of a rabies monoclonal antibody therapeutic in North America.

Grifols Inc – Distribution Agreement for Td vaccine in USA and Canada, effective 7/1/2015

Sale of Reagents: Reagents are by-products of the major manufacturing products of MassBiologics. MassBiologics makes these reagents available for research purposes.

e. Revenues, expenditures, assets and liabilities

On the pages that follow, please find two schedules: (1) FY15 Statement of Revenues and Expenditures and Other Charges, and (2) FY15 Balance Sheet. This information is reviewed as part of the University of Massachusetts annual audit and is included as part of comprehensive financial reports made to the University of Massachusetts' Board of Trustees. Financial activities are also reported to the Office of the State Comptroller.

When reviewing these schedules, please note:

- State Appropriations / DPH represents the DPH appropriated fund support of the effort at the Biologic Laboratories of \$802,685. These funds only partially support staff and provide the supplies and equipment used in the production of vaccine which is distributed to residents of Massachusetts without charge. The vaccine that is provided is Tetanus-Diphtheria vaccine (Td).
- License and Royalty Fees represents such payments received for CMV-IGIV, and monoclonal antibodies to RSV and *C. difficile*.

The Plant Fund is to cover the replacement of major equipment, essential facility improvements necessary to meet FDA and other manufacturing license requirements. This account includes the cumulative capitalized equipment purchases and building improvements and a balance of unexpended funds in reserve for planned equipment purchases and building improvements. In FY15, the plant fund continued to also be used to conclude the new facility expenses.

The core activities of MassBiologics remained consistent through FY15. In calendar year 2008 the MassBiologics received its licensure from the FDA to bring its new production facility on line. MassBiologics continued to manufacture clinical material in the new facility to support its IND activities.

The new production facility is located at the old Boston State Hospital location. This location was authorized by the legislature in July 2000 and opened October 2005. To support the costs of the new facility, Worcester City Campus Corporation borrowed in FY02 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of MassBiologics. The plant fund represents payment of the lease payments supporting the bonds, as well as other capital costs associated with Worcester City Campus Corporation, the University of Massachusetts Medical School and the capital needs and operations of MassBiologics.

Construction of Mattapan II was completed in the late spring of 2010. The project was on time and within budget. Mattapan II was also occupied in this timeframe.

To support the costs of Mattapan II, Worcester City Campus Corporation borrowed \$35 million in FY 07 in reliance on its lease with the University of Massachusetts Medical School acting on behalf of the MassBiologics.

It was determined that MassBiologics would benefit from consolidating its operations to one campus by making facilities modifications to the Mattapan Campus. Modifications completed by June 2013 made it possible for MassBiologics to leave the Jamaica Plain Campus effective June 30, ending a 119 year tenancy at that campus. Commissioning and validation activities are ongoing and it is expected that Td vaccine manufactured in the newly created space will be available for release and human use by the end of fiscal 2015.

In fiscal 2015 it was determined that the MAB facility developed under the guidance of the UMass Dartmouth campus would be a better strategic fit if it were configured as a cGMP manufacturing resource for the development of vectored therapeutics under the operational control of MassBiologics. To that end the previously identified grants totaling \$10M from the MLSC and MassWorks are being invested in the facility located at 1240 Innovation Way to support the cGMP requirements of vector manufacturing.

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2014 Through June 30, 2015

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	16,751,153		16,751,153
Restricted Grants & Contracts	8,512,520		8,512,520
State Appropriations/DPH		769,748	769,748
Royalty Fees and Interest	23,920,921		23,920,921
Recovery of Indirect Costs	526,667		526,667
Other Income	1,091,306		1,091,306
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Total Revenue and Other Additions	50,802,567	769,748	51,572,315
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	16,971,716	412,339	17,384,055
Fringe Benefits	5,004,296	112,007	5,116,303
Supplies and Services	26,493,766	245,402	26,739,168
Depreciation	1,739,911		1,739,911
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Total Expenditures and Other Deductions	50,224,503	769,748	50,994,251
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Net Increase/(Decrease) Before Transfers	578,064	0	578,064
Nonmandatory Transfers			
Transfers	20,600,000	0	20,600,000
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Total Transfers	20,600,000	0	20,600,000
	<hr/>		
Other Changes			
Excess of Restricted Receipts over Transfers to Revenue	0	0	0
NET INCREASE(DECREASE) FOR THE YEAR			
	21,178,064	0	21,178,064
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Fund Balances at Beginning of Year (7/1/14)	42,719,943	0	42,719,943
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FUND BALANCES AT END OF YEAR	63,898,007	0	63,898,007
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University of Massachusetts Biologic Laboratories
Balance Sheet
As of June 30, 2015
(Unaudited)

	CURRENT FUND FY15	PLANT FUND FY15	TOTAL FY15
Assets			
Cash	11,744,700	1,112,929	12,857,629
Accounts Receivable	19,834,638		19,834,638
Inventory	8,203,313		8,203,313
Prepaid Expenses	182,905	244,705	427,610
Buildings & Equipment		26,627,633	26,627,633
Other Assets			
Total Assets	39,965,556	27,985,264	67,950,823
Liabilities			
Accounts Payable	3,078,134	158,154	3,236,288
Employee-Related Accruals	816,528		816,528
Other Liabilities			
Total Liabilities	3,894,662	158,154	4,052,816
Fund Balances	36,070,894	27,827,113	63,898,007
Total Liabilities and Fund Balance	39,965,556	27,985,267	67,950,823

Financial Plans

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2015 Through June 30, 2016

(Unaudited)

	CURRENT	APPROPRIATED	
	FUND	FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	27,067,555		27,067,555
Restricted Grants & Contracts	5,823,105		5,823,105
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	46,143,792		46,143,792
Recovery of Indirect Costs	583,636		583,636
Other Income	318,220		318,220
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Total Revenue and Other Additions	79,936,308	802,685	80,738,993
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	20,388,666	412,339	20,801,005
Fringe Benefits	6,315,487	112,007	6,427,494
Supplies and Services	38,590,283	278,339	38,868,622
Depreciation	2,216,955		2,216,955
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Total Expenditures and Other Deductions	67,511,391	802,685	68,314,076
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Net Increase/(Decrease) Before Transfers	12,424,917	0	12,424,917
Nonmandatory Transfers			
Transfers	4,355,000	0	4,355,000
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Total Transfers	4,355,000	0	4,355,000
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Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	16,779,917	0	16,779,917
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Fund Balances at Beginning of Year (7/1/15)	63,898,007	0	63,898,007
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FUND BALANCES AT END OF YEAR	80,677,924	0	80,677,924
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**University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2016 Through June 30, 2017**

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	24,544,815		24,544,815
Restricted Grants & Contracts	4,128,105		4,128,105
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	46,970,447		46,970,447
Recovery of Indirect Costs	583,636		583,636
Other Income	396,800		396,800
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Total Revenue and Other Additions	76,623,803	802,685	77,426,488
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	21,738,037	412,339	22,150,376
Fringe Benefits	6,732,426	112,007	6,844,433
Supplies and Services	39,852,214	278,339	40,130,553
Depreciation	2,729,243		2,729,243
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Total Expenditures and Other Deductions	71,051,920	802,685	71,854,605
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Net Increase/(Decrease) Before Transfers	5,571,883	0	5,571,883
Nonmandatory Transfers			
Transfers	0	0	0
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Total Transfers	0	0	0
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Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
NET INCREASE(DECREASE) FOR THE YEAR	5,571,883	0	5,571,883
Fund Balances at Beginning of Year (7/1/16)	80,677,924	0	80,677,924
FUND BALANCES AT END OF YEAR	86,249,807	0	86,249,807

University of Massachusetts Biologic Laboratories
Statement of Revenues, Expenditures and Other Changes
For the Period July 1, 2017 Through June 30, 2018

(Unaudited)

	CURRENT FUND	APPROPRIATED FUNDS	TOTAL
REVENUE AND OTHER ADDITIONS:			
Product Sales	26,127,711		26,127,711
Restricted Grants & Contracts	4,128,105		4,128,105
State Appropriations/DPH		802,685	802,685
Royalty Fees and Interest	46,102,280		46,102,280
Recovery of Indirect Costs	583,636		583,636
Other Income	550,471		550,471
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Total Revenue and Other Additions	77,492,203	802,685	78,294,888
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EXPENDITURES AND OTHER DEDUCTIONS:			
Salaries	21,955,429	412,339	22,367,768
Fringe Benefits	6,799,618	112,007	6,911,625
Supplies and Services	45,251,694	278,339	45,530,033
Depreciation	3,006,128		3,006,128
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Total Expenditures and Other Deductions	77,012,869	802,685	77,815,554
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Net Increase/(Decrease) Before Transfers	479,334	0	479,334
Nonmandatory Transfers			
Transfers	0	0	0
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Total Transfers	0	0	0
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Other Changes			
Excess of Restricted Receipts over Transfers to Revenue			
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NET INCREASE(DECREASE) FOR THE YEAR	479,334	0	479,334
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Fund Balances at Beginning of Year (7/1/17)	86,249,807	0	86,249,807
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FUND BALANCES AT END OF YEAR	86,729,141	0	86,729,141
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